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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,266	11/14/2003	Richard Bruce Brandon	40383-0006	7950
61263	7590	03/25/2010	EXAMINER	
PROSKAUER ROSE LLP One International Place Boston, MA 02110			SMITH, CAROLYN L	
			ART UNIT	PAPER NUMBER
			1631	
			MAIL DATE	DELIVERY MODE
			03/25/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/712,266	Applicant(s) BRANDON ET AL.	
	Examiner Carolyn Smith	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 71-78,80-93,95 and 147 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 71-78,80-93,95 and 147 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>06262009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendments and remarks, filed 9/17/09, are acknowledged. Amended claims 71-76, 80-81, 83-93, cancelled claims 1-70, 79, 94, and 96-146 and new claim 147 are acknowledged.

Applicant's arguments, filed 9/17/09, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 71-78, 80-93, 95 and 147 are herein under examination.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 71-78, 80-93, and 95 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. This rejection is maintained and reiterated for reasons of record.

Claims 71-78, 80-93, and 95 are drawn to a process. A process is statutory subject matter under 35 U.S.C. 101 if: (1) it is tied to a particular machine or apparatus or (2) it transforms an article to a different state or thing (In re Bilski, 88 USPQ2d 1385 Fed. Cir. 2008).

The claimed subject matter is not limited to a particular apparatus or machine. To qualify as a statutory process, the claims should require use of a machine within the steps of the claimed

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subject matter or require transformation of an article to a different state or thing. Insignificant extra-solution activity in the claimed subject matter will not be considered sufficient to convert a process that otherwise recites only mental steps into statutory subject matter (In re Grams 12 USPQ2d 1824 Fed. Cir. 1989). Preamble limitations that require the claimed process to comprise machine implemented steps will not be considered sufficient to convert a process that otherwise recites only mental steps into statutory subject matter. It is noted that the instant claim 71 recites "comparing the subject data"; however, this step is not a transformation of an article to a different state or thing. It is further noted that claims 71-78, 80-93, and 95 do not explicitly require that the steps of the claimed method are performed on a machine. Applicant is cautioned against introduction of new matter in an amendment.

Applicant argues that claim 71 has been amended which requires the steps to be performed on a machine. This statement is found unpersuasive as a "system" is not necessarily a machine (without specifically reciting clear structural limitations). One way to overcome this method is to recite "using a computer" in one or more critical steps of instant claim 71, such as the comparing or determining steps.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Australia on 11/14/02. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections – 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 71-78, 80-93, 95 and 147 are rejected under 35 U.S.C. 102(e) as being anticipated by Hamilton et al. (US 2003/0229451 A1). This rejection is maintained for claims 71-78, 80-93, and 95 and necessitated by amendment for claim 147.

Hamilton et al. disclose an apparatus and method of determining the status of a subject using a system including an end station coupled to a base station via a communications network (abstract, 0013, 0018, 0022, Figure 5, 0097-0109) including obtaining subject data from cells from a single test including values of a plurality of parameters representative of gene expression product levels and indicative of the subject's status (0013-0017, 0054-0071), in a base station receiving subject data from the end station via the communications network (0022, Figure 5, 0100-0109, 0113, 0141), comparing the subject data to predetermined data (i.e. reference data) and determining the status of the subject indicating the presence, absence or degree of one or more conditions (0017, 0072-0075, 0080-0081, 0133), and transferring the status indication to the end station (0022, Figure 5, 0100-0121, 0113, 0147), as stated in instant claim 71, as well as medical practitioner confirmation (0061-0062), as stated instant claim 85. Hamilton et al.

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disclose the indication of a stage of a condition (0080, 0087), as stated in instant claim 72.

Hamilton et al. disclose parameter numbers being sufficiently statistically significant to allow a number of conditions to be distinguished (0043, 0086), as stated in instant claim 73. Hamilton et al. disclose parameters being greater than 100, 1000, or less than 6000 parameters (0068, 0135, 0148, 0259), as stated in instant claims 74-76. Hamilton et al. disclose generating a report representing the status of the subject (0013, 0017, 0022, 0090, 0100, 0114, 0190), as stated in instant claim 77. Hamilton et al. disclose validating drug compounds and producing a compilation of health or wellness profiles including assessing health outcomes such as general health, physical function, role of function due to physical limitations, vitality and energy (abstract, 0009, 0054-0055, 0062, 0075) which represents determining the ability to perform in a sporting event in accordance with the presence or absence of a condition, as stated in instant claim 78. Hamilton et al. disclose levels of genes and proteins (0055). Hamilton et al. disclose reference data including phenotypic data of individuals and subject data including phenotypic data (0052, 0053, 0057, 0060, 0017), as stated in instant claim 81. Hamilton et al. disclose comparing subject data to predetermined (i.e. reference) data having one or more phenotypic traits in common with the subject (0013, 0043, 0080), as stated in instant claim 82. Hamilton et al. disclose predetermined data being diagnostic signatures, including determining a diagnostic signature for a respective condition by data mining subject data related to individuals with known conditions or degrees of conditions including a range of values for some parameters (0013, 0017, 0071, 0080-0082, 0085-0087, 0091, 0133), as stated in instant claim 83. Hamilton et al. disclose data determined by clinical trials and diagnosis of conditions within subjects (0061, 0385, 0054, 0062, 0071, 0080), as stated in instant claim 84. Hamilton et al. disclose

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determining a diagnostic signature by obtaining data relating to individuals including indication status, respective values for parameters, selecting one or more groups, and determining a range of parameters values for each group in accordance to values and range representing a diagnostic signature (0013, 0017, 0071, 0080-0082, 0085-0087, 0091, 0120 (i.e. different distributional parameters), 0133, 0030, 0039, 0136-0139, 0143-0144, 0148-0149, i.e. clustering inherently selectively excludes, 0129, 0134, 0208, 0397), as stated in instant claim 86, as well as the comparing and excluding steps in instant claim 87, medical practitioner confirmation (0061-0062), comparing (0017), and updating (0088), as stated in instant claim 88, as well as comparing and excluding steps in instant claim 90. Hamilton et al. disclose predetermined criteria using quality control criteria (0120), as stated in instant claim 89. Hamilton et al. disclose determining parameters that allow a group to be distinguished from each other group as well as determining parameters that allow the degree of a condition to be determined and determining a range of parameter values (0013, 0017, 0043, 0060-00610071, 0080-0082, 0085-0087, 0091, 0133, 0030, 0039, 0136-0139, 0143-0144, 0148-0149), as stated in instant claims 91 and 92. Hamilton et al. disclose obtaining data for an individual, comparing parameter values for the individual to the respective diagnostic signature and revising the diagnostic signature in accordance with an unsuccessful comparison (0086-0088 (i.e. refining diagnostic signature), 0013, 0017, 0053, 0080-0083), as stated in instant claim 93. Hamilton et al. disclose using a system including an end station coupled to a base station via communications network to receive data, determine status, and transfer indication of status to the end station via the network (0018, 0022, 0098-0099, 0100, 0102-0120). Hamilton et al. disclose subjects and individuals such as humans, equines, canines (0057), as stated in instant claim 95.

Thus, Hamilton et al. anticipate the instant invention.

Applicant summarizes Hamilton et al. and argues that they do not describe the process of performing a diagnosis based on comparisons of subject data to coherent data sets, specifically the comparing and determining steps of instant claim 71. This statement is found unpersuasive as Hamilton et al. disclose obtaining subject data from cells from a single test including values of a plurality of parameters representative of gene expression product levels and indicative of the subject's status (0013-0017, 0054-0071) and stage of a condition (0080, 0087), as well as comparing the subject data to predetermined data (i.e. reference data) and determining the status of the subject indicating the presence, absence or degree of one or more conditions (0017, 0072-0075, 0080-0081, 0133). Applicant states that claim 71 has been amended and argues that Hamilton et al. do not disclose a specific end station and base station limitations that are coupled via a communications network wherein data is submitted and received with the status indication results being transferred to the end station. This statement is found unpersuasive as Hamilton et al. disclose an apparatus and method of determining the status of a subject using a system including an end station coupled to a base station via a communications network (abstract, 0013, 0018, 0022, Figure 5, 0097-0109) including obtaining subject data from cells from a single test including values of a plurality of parameters representative of gene expression product levels and indicative of the subject's status (0013-0017, 0054-0071), in a base station receiving subject data from the end station via the communications network (0022, Figure 5, 0100-0109, 0113, 0141), comparing the subject data to predetermined data (i.e. reference data) and determining the status of the subject indicating the presence, absence or degree of one or more conditions (0017, 0072-

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0075, 0080-0081, 0133), and transferring the status indication to the end station (0022, Figure 5, 0100-0121, 0113, 0147). In the paragraphs and Figure cited above, Hamilton discusses sending and receiving data (0113), the use of a communications network with databases, data processing, data analysis tools, and user interfaces (see Figure 5 and paragraph 0022), servers and operating systems (0103-0104, 0109), and the use of the internet and various external databases accessed through a WWW connection (0104 and 0109). Applicant's arguments are deemed unpersuasive for the reasons given above.

Other prior art

Although not being used as prior art, US 2004/0009479 has been made of record. In US 2004/0009479, Wohlgemuth et al. discuss diagnosing and monitoring auto immune diseases via gene expression level detection.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. If you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, please call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on (571) 272-0720.

December 29, 2009

/Carolyn Smith/
Primary Examiner
AU 1631